

BEFORE THE IOWA BOARD OF PHARMACY

RE: Application for Limited Distributor License of SURMASIS PHARMACEUTICAL Applicant	LICENSURE BY CONSENT AGREEMENT
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COME NOW the Iowa Board of Pharmacy ("Board") and Surmasis Pharmaceutical ("Applicant"), 4020 Gannett Ave, Des Moines IA 50321, and enter into this Licensure by Consent Agreement, pursuant to Iowa Code sections 17A.10 and 17A.18 (2020). The Board has jurisdiction over Applicant and the subject matter of this case pursuant to Iowa Code chapters 17A and 155A, and 657 IAC chapter 42.

A. LEGAL GROUNDS

1. The law prohibits the wholesale distribution in or into Iowa of a prescription drug by a manufacturer without a wholesaler or limited distributor license. Iowa Code § 155A.42(1)(c) and 657 IAC 42.3(1)"c".
2. A wholesale distributor may not operate or do business in Iowa with a delinquent license. 657 IAC 17.3(2)"b".
3. The Board may deny a limited distributor license for noncompliance with the licensing requirements under previously granted licenses. 657 IAC 36.6(5).

B. FACTUAL CIRCUMSTANCES

4. Applicant previously held wholesaler license number 7688, which expired on December 31, 2018.
5. On November 20, 2020, Applicant submitted an initial license application for a limited distributor license.
6. On or about November 23, 2020, Applicant shipped prescription drugs to a wholesaler's selected warehousing company, requesting that the product be quarantined. The prescription drugs have been quarantined and have not been distributed to retailers or customers.
7. Applicant does not have a current wholesaler or limited distributor license.

C. LICENSURE BY CONSENT

8. While Applicant alleges it acted in a good faith belief in its interpretation of the applicable administrative rules, Applicant acknowledges that the allegations in the Factual Circumstances, if proven in a contested case hearing concerning license denial, and if the administrative rules are interpreted to apply to these facts, could be found to constitute grounds for the adverse action agreed to in this Agreement.

9. Execution of this Agreement constitutes the resolution of a contested case. Applicant has a right to hearing before the Board on the grounds for license denial, but Applicant waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's action, by freely and voluntarily entering into this Agreement. Once entered, this Agreement shall have the force and effect of a Board Order entered following a contested case hearing concerning license denial.

10. Applicant acknowledges that it has the right to be represented by counsel on this matter.

11. This Agreement is subject to approval by a majority of the full Board. If the Board does not approve this Agreement, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Agreement, it shall be the full and final resolution of this matter.

12. This Agreement shall be part of Applicant's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

13. Applicant understands that this Agreement constitutes adverse action and that the Board is required by federal law to report any adverse action to the National Practitioner Data Bank.

14. This Agreement, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.

15. The Board's approval of this Agreement shall constitute a **FINAL ORDER** of the Board.

IT IS THEREFORE ORDERED:

16. Applicant shall be issued a limited distributor license.

17. Applicant is hereby **CITED** for engaging in limited wholesale distribution prior to proper licensure and **WARNED** that future violations of the laws and rules governing distribution can result in further disciplinary action.


18. Applicant shall pay a **CIVIL PENALTY** in the amount of one thousand dollars (\$1,000) within 30 days of Board approval of this Agreement. The check shall be made payable to the "Treasurer of Iowa" and shall be deposited in the general fund. The payment should be mailed to the Iowa Board of Pharmacy, Attn: Amanda Woltz, 400 SW 8th St, Ste E, Des Moines IA 50309.

19. Should Applicant violate the terms of this Agreement, the Board may initiate action to impose licensee discipline as authorized by Iowa Code chapter 155A and 657 IAC chapter 36.


By the signature below, signatory acknowledges they are authorized to sign this Licensure by Consent Agreement on behalf of Applicant.

12-15-2020

Date


SURMASIS PHARMACEUTICAL
Applicant

This Licensure by Consent Agreement is approved by the Iowa Board of Pharmacy on
December 16, 2020.


Chairperson
Iowa Board of Pharmacy